## SAFETY DATA SHEETS

This SDS packet was issued with item: 073429743

N/A



### Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830Date of issue: 1-7-2014Revision date: 19-9-2016Supersedes: 1-7-2014 Version: 2.0

| SECTION 1: Identification of the                       | substance/mixture and of the company/undertaking   |
|--|--|
| 1.1. Product identifier                                |  |
| Product form   | : Mixture  |
| Product name   | : Tubulitec Primer   |
| Product group  | : Trade product  |
| 1.2. Relevant identified uses of the                   | substance or mixture and uses advised against  |
| 1.2.1. Relevant identified uses                        |  |
| Main use category                                      | : Professional use   |
| Use of the substance/mixture                           | : For isolation of cavities  |
| Use of the substance/mixture                           | : Dentistry  |
| Title  | Use descriptors  |
| Tubulitec Primer                                       | SU20   |
|  |  |
| Full text of use descriptors: see section 16           |  |
| 1.2.2. Uses advised against                            |  |
| No additional information available                    |  |
| 1.3. Details of the supplier of the sa                 | afety data sheet   |
| Dental Therapeutics AB                                 |  |
| Paviljongvägen 3-5                                     |  |
| SE-13240 SALTSJO-BOO - Sweden<br>T +46(0)8 12 29 69 21 |  |
| info@therapeutics.se - www.therapeutics.s              | e  |
| 1.4. Emergency telephone number                        |  |
| Emergency number                                       | : National Poisons Information Centre +31 (0)30 - 274 8888   |
|  | (Only for the purpose of informing medical personnel in cases of accidental intoxications. The                   |
|  | emergency phone number is 24 hours/day available.)   |
| SECTION 2: Hazards identification                      | on   |
| 2.1. Classification of the substance                   | e or mixture   |
| Classification according to Regulation (I              | EC) No. 1272/2008 [CLP]  |
| Flammable liquids, Category 2                          | H225   |
| Full text of H statements : see section 16             |  |
|  |  |
| Adverse physicochemical, human health                  | n and environmental effects  |
| No additional information available                    |  |
| 2.2. Label elements                                    |  |
| Labelling according to Regulation (EC)                 | No. 1272/2008 [CLP]  |
| Hazard pictograms (CLP)                                |  |
|  |  |
|  |  |
|  |  |
|  | GHS02  |
| Signal word (CLP)                                      | : Danger   |
| Hazard statements (CLP)                                | : H225 - Highly flammable liquid and vapour  |
| Precautionary statements (CLP)                         | : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No                   |
| · · · · ·  | smoking  |
|  | P233 - Keep container tightly closed<br>P501 - Dispose of contents/container to an approved waste disposal plant |
|  |  |
|  |  |
| 2.3. Other hazards                                     |  |

#### 2.3. Other hazards

#### No additional information available

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

#### Not applicable

#### 3.2. Mixtures

| Name  | Product identifier  | Conc.<br>(% w/w) | Classification according to<br>Regulation (EC) No.<br>1272/2008 [CLP] |
|---|---|------------------|---|
| Ethanol<br>substance with national workplace exposure limit(s) (GB) | (CAS-No.) 64-17-5<br>(EC-No.) 200-578-6<br>(EC Index-No.) 603-002-00-5<br>(REACH-no) 01-2119457610-43 | 75-100           | Flam. Liq. 2, H225  |

#### Full text of H-statements: see section 16

| SECTION 4: First aid measures                    |  |
|--|--|
| 4.1. Description of first aid measures           |  |
| First-aid measures general                       | : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).  |
| First-aid measures after inhalation              | : If you feel unwell, seek medical advice.   |
| First-aid measures after skin contact            | : Wash with plenty of soap and water. Hand protection : skin cream may be used.  |
| First-aid measures after eye contact             | : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  |
| First-aid measures after ingestion               | : Give milk to drink. On ingestion in large quantities: Get medical advice/attention.  |
| 4.2. Most important symptoms and effect          | cts, both acute and delayed  |
| Symptoms/effects after inhalation                | : High concentration of vapours may induce: headache, dizziness, drowsiness, nausea and vomiting.  |
| 4.3. Indication of any immediate medica          | I attention and special treatment needed   |
| No additional information available              |  |
| SECTION 5: Firefighting measures                 |  |
| 5.1. Extinguishing media                         |  |
| Suitable extinguishing media                     | : Powder. Carbon dioxide (CO2). Water spray.   |
| Unsuitable extinguishing media                   | : Do not use a heavy water stream.   |
| 5.2. Special hazards arising from the su         | bstance or mixture   |
| Fire hazard                                      | : Flammable.   |
| Reactivity in case of fire                       | : The vapours mix well with air, explosive mixtures are easily formed.   |
| Hazardous decomposition products in case of fire | : Combustion produces toxic gases. Carbon monoxide. Carbon dioxide.  |
| 5.3. Advice for firefighters                     |  |
| Firefighting instructions                        | : Fight fire with normal precautions from a reasonable distance. Cool down the containers exposed to heat with a water spray.  |
| Protection during firefighting                   | : Do not enter fire area without proper protective equipment, including respiratory protection.  |
| <b>SECTION 6: Accidental release mea</b>         | sures  |
|  | uipment and emergency procedures   |
| General measures                                 | : Concerning personal protective equipment to use, see section 8. Ensure adequate air ventilation. Avoid all eye and skin contact and do not breathe vapour and mist. Access forbidden to unauthorised personnel. No flames, no sparks. Eliminate all sources of ignition. |
| 6.1.1. For non-emergency personnel               |  |
| No additional information available              |  |
| 6.1.2. For emergency responders                  |  |
| No additional information available              |  |
| 6.2. Environmental precautions                   |  |
| Avoid release to the environment. Prevent soil a | nd water pollution.  |
| 6.3. Methods and material for containing         | ent and cleaning up  |
| Methods for cleaning up                          | : Collect all waste in suitable and labelled containers and dispose according to local legislation.<br>Contaminated surfaces: clean (treat) with an excess of water.   |
|  |  |

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#### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Concerning disposal elimination after cleaning, see section 13.

| <b>SECTION 7: Handling and storage</b> | je  |
|--|---|
| 7.1. Precautions for safe handling     |   |
| Additional hazards when processed      | : Highly flammable.   |
| Precautions for safe handling          | <ul> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No<br/>smoking. Carefully comply with the instructions for use. Do not eat, drink or smoke when using<br/>this product. Keep out of the reach of children. Try to stop release if without risk. See Heading</li> <li>Take precautionary measures against static discharge. Keep container tightly closed. Ensure<br/>good ventilation of the work station.</li> </ul> |
| Hygiene measures                       | : Remove contaminated clothes.  |
| 7.2. Conditions for safe storage, in   | cluding any incompatibilities   |
| Storage conditions                     | : Emergency safety showers should be available in the immediate vicinity of any potential exposure.   |
| Storage temperature                    | : Store at ambient temperature  |
| Information on mixed storage           | : Oxidizer.   |
| 7.2 Specific and use(c)                |   |

7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Ethanol (64-17-5) |                               |                                     |
|-------------------|-------------------------------|-------------------------------------|
| United Kingdom    | Local name                    | Ethanol                             |
| United Kingdom    | WEL TWA (mg/m <sup>3</sup> )  | 1920 mg/m <sup>3</sup>              |
| United Kingdom    | WEL TWA (ppm)                 | 1000 ppm                            |
| United Kingdom    | WEL STEL (mg/m <sup>3</sup> ) | 5760 mg/m <sup>3</sup> (calculated) |
| United Kingdom    | WEL STEL (ppm)                | 3000 ppm (calculated)               |
| United Kingdom    | Regulatory reference          | EH40. HSE                           |

| Ethanol (64-17-5)                        |                          |  |
|--|--------------------------|--|
| DNEL/DMEL (Workers)                      |                          |  |
| Acute - local effects, inhalation        | 1900 mg/m <sup>3</sup>   |  |
| Long-term - systemic effects, dermal     | 343 mg/kg bodyweight/day |  |
| Long-term - systemic effects, inhalation | 950 mg/m³                |  |
| DNEL/DMEL (General population)           |                          |  |
| Acute - local effects, inhalation        | 950 mg/m³                |  |
| Long-term - systemic effects,oral        | 87 mg/kg bodyweight/day  |  |
| Long-term - systemic effects, inhalation | 114 mg/m <sup>3</sup>    |  |
| Long-term - systemic effects, dermal     | 206 mg/kg bodyweight/day |  |
| PNEC (Water)                             |                          |  |
| PNEC aqua (freshwater)                   | <= 0,96 mg/l             |  |
| PNEC aqua (marine water)                 | 0,79 mg/l                |  |
| PNEC aqua (intermittent, freshwater)     | 2,75 mg/l                |  |
| PNEC (Sediment)                          |                          |  |
| PNEC sediment (freshwater)               | 3,6 mg/kg dwt            |  |
| PNEC sediment (marine water)             | 2,9 mg/kg dwt            |  |
| PNEC (Soil)                              |                          |  |
| PNEC soil                                | 0,63 mg/kg dwt           |  |
| PNEC (Oral)                              |                          |  |
| PNEC oral (secondary poisoning)          | 0,72 g/kg                |  |
| PNEC (STP)                               |                          |  |
| PNEC sewage treatment plant              | 580 mg/l                 |  |
| 8.2. Exposure controls                   |                          |  |

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Personal protective equipment:

In case of splash hazard: safety glasses.

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#### Hand protection:

No special clothing/skin protection equipment is recommended under normal conditions of use

#### Eye protection:

If there is a risk of liquid being splashed : Safety glasses

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.



#### Environmental exposure controls:

SECTION 12.

| SECTION 9: Physical and chemical properties |                                      |  |
|---|--------------------------------------|--|
| 9.1. Information on basic physical and      | chemical properties                  |  |
| Physical state                              | : Liquid                             |  |
| Colour                                      | : Yellow.                            |  |
| Odour                                       | : Alcohol odour.                     |  |
| Odour threshold                             | : No data available                  |  |
| pH  | : No data available                  |  |
| Relative evaporation rate (butylacetate=1)  | : No data available                  |  |
| Melting point                               | : No data available                  |  |
| Freezing point                              | : No data available                  |  |
| Boiling point                               | : 78 °C                              |  |
| Flash point                                 | : 13 °C                              |  |
| Auto-ignition temperature                   | : No data available                  |  |
| Decomposition temperature                   | : No data available                  |  |
| Flammability (solid, gas)                   | : Highly flammable liquid and vapour |  |
| Vapour pressure                             | : 5,87 kPa                           |  |
| Relative vapour density at 20 °C            | : No data available                  |  |
| Relative density                            | : 1,6                                |  |
| Density                                     | : 7,91 Relative density              |  |
| Solubility                                  | : No data available                  |  |
| Log Pow                                     | : No data available                  |  |
| Viscosity, kinematic                        | : No data available                  |  |
| Viscosity, dynamic                          | : No data available                  |  |
| Explosive properties                        | : No data available                  |  |
| Oxidising properties                        | : No data available                  |  |
| Explosive limits                            | : 3,5 - 11,5 vol %                   |  |
| 9.2. Other information                      |                                      |  |

#### No additional information available

| SECTION 10: Stability and reactivity   |                |
|--|----------------|
| 10.1. Reactivity   |                |
| Keep away from oxidizing agents.   |                |
| 10.2. Chemical stability   |                |
| Stable under normal conditions.  |                |
| 10.3. Possibility of hazardous reactions   |                |
| May form explosive compounds. Reacts vigorously with strong oxidizers and acids. Reacts with : Hydrogen peroxide | , Nitric acid. |
| 10.4. Conditions to avoid  |                |
| Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.                   |                |
| 10.5. Incompatible materials   |                |
| Attacks some forms of plastic, rubbar and eastings   |                |

Attacks some forms of plastic, rubber and coatings.

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#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

| SECTION 11: Toxicological informa                                  |  |
|--|--|
| 11.1. Information on toxicological effect<br>Acute toxicity (oral) | s . Not classified   |
|  |  |
| Acute toxicity (dermal)  | : Not classified   |
| Acute toxicity (inhalation)  | : Not classified   |
| Ethanol (64-17-5)  |  |
| LD50 oral rat  | 10470 mg/kg (Symptoms may include dizziness, headache, nausea and loss of coordination)  |
| LD50 dermal rabbit   | > 2000 mg/kg (Symptoms: Redness, pain)   |
| LC50 inhalation rat (mg/l)   | 124,7 mg/l/4h (Symptoms include headache, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness) |
| Skin corrosion/irritation  | : Not classified   |
| Serious eye damage/irritation                                      | : Not classified   |
| Respiratory or skin sensitisation                                  | : Not classified   |
| Germ cell mutagenicity   | : Not classified   |
| Carcinogenicity  | : Not classified   |
| Reproductive toxicity  | : Not classified   |
| STOT-single exposure   | : Not classified   |
| STOT-repeated exposure   | : Not classified   |
| Ethanol (64-17-5)  |  |
| NOAEL (oral, rat, 90 days)   | 4 ml/kg (male)   |
| Aspiration hazard  | : Not classified   |
| Potential adverse human health effects and symptoms                | : Based on available data, the classification criteria are not met.  |
| <b>SECTION 12: Ecological informatio</b>                           | n  |
| 12.1. Toxicity   |  |
| Ecology - general  | : Ecological problems are not known or expected under normal use.  |
| Acute aquatic toxicity   | : Not classified   |
| Chronic aquatic toxicity   | : Not classified   |
| Ethanol (64-17-5)  |  |
|  |  |

| LC50 fishes        | 14,2 g/l   |
|--------------------|--|
| LC50 fish 2        | 13000 mg/l (Oncorhynchus mykiss (Rainbow trout)) |
| EC50 Daphnia       | 12340 mg/l                                       |
| EC50 72h algae (1) | 275 mg/l Chlorella vulgaris                      |
| NOEC (chronic)     | > 1 mg/l 24d                                     |

#### 12.2. Persistence and degradability

| Ethanol (64-17-5)                   |                        |
|-------------------------------------|------------------------|
| Persistence and degradability       | Readily biodegradable. |
| 12.3. Bioaccumulative potential     |                        |
| Ethanol (64-17-5)                   |                        |
| Log Pow                             | -0,32                  |
| Bioaccumulative potential           | No bioaccumulation.    |
| 12.4. Mobility in soil              |                        |
| No additional information available |                        |

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

No additional information available

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|--|--|--|
| SECTION 13: Disposal consid  | derations  |  |
| 13.1. Waste treatment methods  |  |  |
| Regional legislation (waste)   | : Disposal must be done according to official regulations.   |  |
| Additional information   | : Hazardous waste due to potential risk of fire.             |  |
| Ecology - waste materials  | : Avoid release to the environment.                          |  |
| SECTION 14: Transport inform   | mation   |  |
| In accordance with ADR   |  |  |
| ADR  |  |  |
| 14.1. UN number  |  |  |
| 1170   |  |  |
| 14.2. UN proper shipping name  |  |  |
| ETHANOL (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)                            |  |  |
| Transport document description (AD   |  |  |
| UN 1170 ETHANOL (ETHYL ALCOHO  | L) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E) |  |
| 14.3. Transport hazard class(es)   |  |  |
| 3  |  |  |
|  |  |  |
| 14.4. Packing group  |  |  |
| II   |  |  |
| 14.5. Environmental hazards  |  |  |
| Dangerous for the environment : No   |  |  |
|  | No supplementary information available                       |  |

#### 14.6. Special precautions for user

| - Overland transport   |                     |
|--|---------------------|
| Classification code (ADR)                                    | : F1                |
| Special provisions (ADR)                                     | : 144, 601          |
| Limited quantities (ADR)                                     | : 11                |
| Excepted quantities (ADR)                                    | : E2                |
| Packing instructions (ADR)                                   | : P001, IBC02, R001 |
| Mixed packing provisions (ADR)                               | : MP19              |
| Portable tank and bulk container instructions (ADR)          | : T4                |
| Portable tank and bulk container special<br>provisions (ADR) | : TP1               |
| Tank code (ADR)  | : LGBF              |
| Vehicle for tank carriage                                    | : FL                |
| Transport category (ADR)                                     | : 2                 |
| Special provisions for carriage - Operation (ADR)            | : S2, S20           |
| Hazard identification number (Kemler No.)                    | : 33                |
| Orange plates  | 33<br>1170          |

Tunnel restriction code (ADR)

: D/E

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1.

#### 15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

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| 3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008   | Ethanol                    |
|--|----------------------------|
| 3(a) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F  | Tubulitec Primer - Ethanol |
| 40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not. | Ethanol                    |

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

| Other information | : DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of |
|-------------------|--|
|                   | the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.  |

| Flam. Liq. 2  | Flammable liquids, Category 2      |                       |  |  |
|---|------------------------------------|-----------------------|--|--|
| H225  | Highly flammable liquid and vapour |                       |  |  |
| SU20  | Health services                    |                       |  |  |
| Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: |                                    |                       |  |  |
| Flam. Liq. 2  | H225                               | On basis of test data |  |  |

#### SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product